

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW HAMPSHIRE

UNITED STATES OF AMERICA

v.

MUSTAFA ARIF

)  
)  
)  
)  
)  
)

No. 1:14-mj-24-DL

**MOTION TO DISMISS**

Now comes counsel, O'Rourke Law Office, PLLC, who respectfully submits this Motion to Dismiss. In support, counsel says as follows:

The defendant, Mustafa Arif, has requested that counsel submit this Motion to Dismiss. The defendant has researched and drafted the body of this motion.

The defendant contends that this matter was improperly charged as Wire Fraud, 18 USC 1343 and that the complaint for Wire Fraud should be dismissed for lack of probable cause. The defendant further asserts that if he violated any federal law, it was the Federal Trade Commission Act, 15 USCS §§ 52-55.

Counsel notes that the defendant has provided additional arguments in support of his motion. However, as the defendant is currently in custody and unable to produce several exhibits, counsel may further supplement this pleading.

Counsel understands that filing this Motion in this manner is not standard. However, counsel does not believe that this Motion is frivolous or a waste of the Court's time.

1. The alleged false pretenses regarding the safety and efficacy of the products that form the focus of this complaint and also the basis for the wire fraud allegation are said to be extracted from the advertising material contained in the websites for the herbal and homeopathic remedies business described as belonging to the defendant.
2. The investigative agency that conducted the investigation and concluded that the statements on these websites are false is the Food and Drug Administration (FDA).
3. The products in question are herbal and homeopathic remedies purported to cure and treat various human diseases and conditions i.e. non-prescription or over the counter (OTC) drugs.
4. Fraud founded in false advertising of non-prescription drugs is an issue that congress specifically intended to be addressed within the statutory scheme laid out in the Wheeler-Lea Amendments of the Federal Trade Commission Act (15 USCS §§ 52-55) under the exclusive jurisdiction of the Federal Trade Commission. Gladys G. Holloway Vs. Bristol-Myers Corp. (485 F.2d 986, 993) (DC Cir, 1972) *“As in prior Congresses, the House was unwilling to accede to the advertising controls embodied in the Senate food and drug bill. Instead of merely striking the offending provisions from S. 5, the House Committee took the further step of revising these paragraphs and engrafting them onto the Trade Commission Act amendments, **thus placing in the hands of the FTC exclusive control over food, drug, and cosmetic advertising.** This legislative amalgam, denominated the Wheeler-Lea Amendments to the Federal Trade Commission Act, passed the House in January 1938, was adopted by the Conference Committee, passed the {485 F.2d 994} Senate, and was signed into law by President Roosevelt on March 21, 1938. Thereafter, shorn of the one-time impediment of the*

*controversial advertising provisions, the Food, Drug, and Cosmetic Act became law on June 25, 1938.*" (Emphasis added).

5. The FTC Act addresses not just deceptive advertising but also advertising practice that amounts to fraud. *"The term "unfair methods of competition," as used in the Federal Trade Commission Act, includes practices opposed to good morals because characterized by deception and fraud."* (Federal Trade Commission v. Beech-Nut Packing Co. 257 U. S. 441, 453, 66 L. ed. 307, 19 A.L.R. 882, 42 Sup. Ct. Rep. 150; Federal Trade Commission v. Winsted Hosiery Co. 258 U. S. 483, 493, 494, 66 L. ed. 729, 734, 42 Sup. Ct. Rep. 384; Federal Trade Commission v. Sinclair Ref. Co. 261 U. S. 463, 475, 67 L. ed. 746, 753, 43 Sup. Ct. Rep. 450; Federal Trade Commission v. Raymond Bros.-Clark Co. 263 U. S. 565, 572, 68 L. ed. 448, 454, 30 A.L.R. 1114, 44 Sup. Ct. Rep. 162; Federal Trade Commission v. Gratz, 253 U. S. 421, 427, 64 L. ed. 993, 995, 40 Sup. Ct. Rep. 572.)
6. The prohibition of false advertising of food, drugs and cosmetics is stated in 15 USC §§ 52 while the penalties for such action with intent to defraud being described in 15 USC §§ 54 and judicial review provisions in 15 USC §§ 45. Hence, not only a specific but also a comprehensive statutory scheme was adopted to remedy fraud rooted in false advertising claims of OTC drugs.
7. The FTC Act provides criminal remedies for false advertising of OTC drugs with intent to defraud with a maximum statutory prison term of 6 months for first offence. *"Any person, partnership, or corporation who violates any provision of section 12(a) [15 USCS § 52(a)] shall, if the use of the commodity advertised may be injurious to health because of results from such use under the conditions prescribed in the advertisement thereof, or under such conditions as are customary or usual, or if such violation is with intent to defraud or mislead, be guilty of a misdemeanor, and upon*

*conviction shall be punished by a fine of not more than \$5,000 or by imprisonment for not more than six months, or by both such fine and imprisonment” (15 USC §§ 54)*

8. Hence, congress explicitly deemed the conduct alleged in the complaint as not amounting in seriousness to a violation of the wire fraud statue.
9. We believe that the extensive reasoning adopted in Ayres Vs. GMC (234 F.3d 524, 522) (11<sup>th</sup> Cir, 2000) is directly applicable here. Reaching the same conclusion in an analogous context, the court noted, *“The Safety Act establishes its own extensive array of administrative remedies for a violation of its notification obligations.”* In addition, *“In light of this extensive administrative scheme, we think it clear that Congress did not intend to equate a violation of the Safety Act's notification requirements in and of itself with the felony of mail or wire fraud.”* The court accepted and recognized that misrepresentations originating out of material omissions of disclosures can be basis for wire and mail fraud. However, since the specific omissions were specifically addressed in the statutory regime of the Safety Act, the court rejected application of mail and wire fraud statues.
10. Similarly in the D.C. Circuit in *Danielsen v. Burnside-Ott Aviation Training Center*, (941 F.2d 1220, 1229) (DC Cir, 1991), affirmed the dismissal of a federal RICO claim based on violations of the Service Contract Act ("SCA"). In *Danielsen*, the plaintiffs argued that the defendants' non-compliance with the contract requirements of the SCA amounted to mail fraud and that this mail fraud was the racketeering activity supporting their RICO claim. The court rejected this argument reasoning that: *“The very fact that Congress enacted the SCA with its complex framework for administrative recovery suggests that Congress did not contemplate that violation of SCA constituted the criminal felony*

*of mail fraud. . . . It would seem likely that either the statute or at least the legislative history would have indicated as much”*

- 11.** It is therefore prayed, pursuant to rule 12(b)(6) of the federal rules of criminal procedure that the complaint be dismissed for failure to state a claim that amounts to wire fraud.
- 12.** Secondly and still notwithstanding above, the comprehensive and specific statutory scheme contained in the FTC Act addressing fraud rooted in false advertising of OTC drugs also contains statutory judicial review provisions of final agency action. (see 15 USCS §§ 45)
- 13.** The statutory review provisions of the FTC Act make challenges to final agency action review able first by the commission itself and then directly in the circuit court of appeals.
- 14.** Hence, the subject matter of the complaint precludes district court jurisdiction at the pre-enforcement stage pursuant to the consistent position of the first circuit derived from *Thunder Basin Coal Co. Vs. Reich* (510 U.S. 200) (1994). *"Within the Federal Mine Safety and Health Amendments Act of 1977 (Mine Act) (30 USCS §§ 801 et seq.), pertaining to coal miners and other miners, a statutory-review scheme set forth in 30 USCS §§ 815, 816, and 823-under which scheme any challenges to the Mine Safety and Health Administration's enforcement measures are reviewed by the Federal Mine Safety and Health Review Commission and then by the appropriate Federal Court of Appeals-prevents a Federal District Court from exercising subject matter jurisdiction over pre-enforcement claims arising under the Mine Act".*
- 15.** See application of the Thunder Basin principle by first circuit in *Northeast Erectors Vs. Secretary of Labor* (62 F.3d 37, 38) (1<sup>st</sup> Cir, 1995) *"This case falls squarely within the holding of Thunder Basin. We hold that the OSH*

*Act's comprehensive administrative review scheme precluded the district court from exercising subject-matter jurisdiction over the present estoppel-based pre-enforcement challenge. The administrative and judicial review procedures in the two acts are nearly identical. Compare 29 U.S.C. § 660(a) with 30 U.S.C. § 816(a)(1). Moreover, like the claim in Thunder Basin, the NEA's estoppel claim is "of the type Congress intended to be reviewed within this statutory structure." Thunder Basin, 114 S. Ct. at 779."*

- 16.** The same was held by the first circuit in *Eastern Bridge, LLC Vs. Chao* (320 F.3d 84, 89) (1<sup>st</sup> cir, 2003) noting clearly *"Committing initial review to the agency is often sensible policy. Because the administrative agency may possess greater expertise with respect to the organic statute, agency review can be more informed and thus more expeditious, and scarce judicial resources can be conserved for other areas of pressing concern."* the same has been held by other circuits like the 6<sup>th</sup> and DC circuits. See for example *Nader Vs. Volpe* (466 F.2d 261) (DC Cir, 1972).
- 17.** The FTC has not undertaken any action in the present case nor sought any enforcement by the court of any commission order. For jurisdictional purposes, no action should be treated the same as pre-enforcement action. The Supreme Court has elaborated comprehensively in *Heckler v. Chaney* (470 U.S. at 832) (1985) *"[a]n agency's decision not to take enforcement action should be presumed immune from judicial review under § 701(a)(2) of the APA"*.
- 18.** It is therefore requested that under the Thunder Basin principle the complaint be dismissed for lack of subject matter jurisdiction pursuant to rule 12(b)(1) of the federal rules of criminal procedure.
- 19.** Notwithstanding above, the FTC has also not certified any attorney in the Attorney General's office pursuant to the certification requirement of 15

USC §§ 56 to ensure any enforcement via court proceedings. As detailed in *United States Vs. St. Regis Paper Co.* (355 F.2d 688, 699) (2 Cir, 1966) *“To conclude, we hold that Congress intended Section 16 of the FTCA to be jurisdictional, not directory”*. Hence, the court lacks subject matter jurisdiction, as the certification requirement is a jurisdictional one before the Attorney General’s office can intervene in the subject matter placed exclusively under the jurisdiction of the FTC.

- 20.** Further, the plaintiff has not filed complaint with the FTC in attempt to exhaust administrative remedies before knocking the door of the honorable court. It may be noted that this is despite the existence of a comprehensive working agreement between the FDA and the FTC on the issue. (See 36 Fed. Reg. 18,539 (1971)) Rather, contrary to all congressional intent in promulgating the FTC Act, the plaintiff has sought direct intervention of court in the matter.
- 21.** The contention that this can conclude to no action at all and allowing an activity the law deems illegal to go on without impediment, then this is not applicable in this case. The government did have ample remedy under the misbranding clauses of the Food, Drug and Cosmetic Act to prohibit such trade in the first place instead of attempting to evoke advertising issues beyond the court’s subject matter jurisdiction at this stage.
- 22.** The investigating agency in this case, the FDA, also had all the opportunity to defer the advertising matter to the Federal Trade Commission in accordance with its aforementioned working agreement with the commission.
- 23.** Even under rules of futility, at least one attempt is required to seek administrative relief. *Gilbert Vs. Cambridge* (932 F.2d 51, 62) (1<sup>st</sup> cir, 1991) *“It follows, {932 F.2d 62} therefore, that the Blevins plaintiffs, having never applied for a removal permit, cannot rely on the futility exception.”*

- 24.** Congress' intent is clear in establishing a detailed statutory scheme to deal with the current subject matter of false advertising of OTC drugs that at least the issue raised in the complaint be first subjected to the remedies outlined in the FTC Act rather than direct and immediate resort to court. As detailed in *Gladys G. Holloway Vs. Bristol-Myers Corp.* (485 F.2d 986, 998) (DC Cir, 1972) "*While the FTC's special expertise may not be raised as a barrier inhibiting the kind of judicial review of agency action that Congress prescribed and contemplated, it does and should inhibit the notion that a court may be injected into the pertinent subject-matter directly, without the benefit of FTC consideration.*" In addition, (485 F.2d 986, 1002) "*We need not dwell long on the possibility of an appeal to a federal equity jurisprudence. In 1938 Congress specifically rejected a proposal for the use of court injunctions against a "nuisance" of false drug advertising in interstate commerce, and instead relied on the FTC for enforcement.*"
- 25.** It is therefore prayed again, that the complaint be dismissed for lack of subject matter jurisdiction pursuant to rule 12(b)(1) of the federal rules of criminal procedure.
- 26.** Notwithstanding any of the above, the complaint also fails to allege any misrepresentation or deceit concerning the non-FDA approved status of the drugs to the consumer.
- 27.** The United States Food, Drug and Cosmetic Act in 21 USC 331(c) specifically prohibits '*The **receipt** in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.*' (Emphasis added) 21 USC 333(a) makes both acts of buying and selling misbranded drugs a class A misdemeanor punishable by up to one year in prison with a maximum fine of one thousand dollars.



- 28.** A willful and knowing buyer of unregulated (non-FDA approved) drugs, as party to an illegal contract, is not a permissible defrauded party for wire fraud even if false pretenses are used to induce the contract. Specifically applicable to the issue at hand, Court of appeals for the seventh circuit noted in *United States Vs. Vitek Supply Corp.* (144 F.3d 476, 491) (7<sup>th</sup> cir, 1998): *“Unlike Switzerland, most of Vitek's direct customers were aware that the premixes contained unapproved drugs. Therefore, **as the government concedes, these customers were not defrauded and the defendants cannot be held liable for their losses.**”* (Emphasis Added)
- 29.** Similarly, in *United States Vs. Andersen* (45 F.3d 217) (7<sup>th</sup> Cir, 1995) the court decided that there was no quantifiable loss where consumers were very pleased with defendant's product, even though defendant sold product without FDA approval and made false statements to consumers about the product. In *United States Vs. Bhutani* (266 F.3d 661, 670) (7<sup>th</sup> Cir, 2001) the honorable court gave the rationale for its judgment in the Andersen case: *“However, the defendant points out that in Andersen we held that the defendant's gain was not the appropriate measure of loss when there was “no clear evidence that customers or consumers suffered any loss.” 45 F.3d at 221. We so held, in part, **because the drugs in that case were sold in hand-labeled containers and the customers were aware that the drugs were not FDA approved.**”* (Emphasis added)
- 30.** This is also consistent with long held principles of law. In *De Lorma Brooks Vs. Warrick Martin* (17 L Ed 732 at 733) (1864) the Supreme Court noted: *“It is contended that the business for which this copartnership was formed, was illegal, and therefore the defendant cannot be called to an accounting of the profits of any illegal business. If it were conceded that the business was illegal, the conclusion contended for would not follow. **Courts of justice will never interfere to***

***enforce an illegal contract, nor sustain an action that can only be sustained by enforcing and giving effect to an illegal agreement...*** *Barney v. Saunders*, 16 How., 543; *McBlair v. Gibbes*, 17 How., 232, 15 L. ed. 131; *Faikney v. Reynous*, 4 Burr, 2069; *Petrie v. Hannay*, 3 T. R., 418; *Armstrong v. Toler*, 11 Wheat., 258; *Thomson v. Thomson*, 7 Ves., 470; *Farmer v. Russell*, 1 Bos. & P., 296, and cases cited; *Sharp v. Taylor*, 2 Ph. Ch., 801; *Tenant v. Elliott*, 1 Bos. & P., 3, and cases cited; *Rice v. Peet*, 15 Johns., 503; *Lane v. Shackford*, 5 N. H., 133; *Kidder v. Hunt*, 1 Pick., 328; *Sherburn v. Fuller*, 5 Mass., 133; *Boyd v. Stone*, 11 Mass., 342; *Mavor v. Pyne*, 2 Car. & P., 91; *Burlingame v. Burlingame*, 7 Cow., 92; *Gillet v. Maynard*, 5 Johns., 85; 13 Johns., 365; *Shute v. Dorr*, 5 Wend., 205; *Richards v. Allen*, 17 Me., 298; *Holbrook v. Armstrong*, <\*pg. 734> 10 Me., 31; *Cabot v. Haskins*, 3 Pick., 95; *Little v. Martin*, 3 Wend., 219; *Freeport v. Bartol*, 3 Me., 340; *Syler v. Eckhart*, 1 Binn., 378; *Billington v. Walsh*, 5 Binn., 129.”

**31.** An action for fraud based on an illegal contract relies upon and affirms the contract. *Harris Vs. Egger* (226 F. 389, 394) (1915) “*Counsel for Egger rightly concede that the present action for fraud and deceit operated at once to affirm and to rely on the contract. Nat. Bank & Loan Company v. Petrie*, 189 U.S. 423, 425, 23 Sup. Ct. 512, 47 L. Ed. 879; *Whiteside v. Brawley*, 152 Mass. 133, 24 N.E. 1088; *United States Trust Co. v. Chicago Terminal T.R. Co.*, 188 Fed. 292, 296, 110 C.C.A. 270 (C.C.A. 7th Cir.); *Talcott, v. Friend*, 179 Fed. 676, 103 C.C.A. 80, 43 L.R.A. (N.S.) 649 (C.C.A. 7th Cir.).”

**32.** Hence, the complaint again fails to state a claim that amounts to wire fraud due to the illegality of the underlying contract and the lack of a defrauded party and is prayed to be dismissed pursuant to rule 12(b)(6) of the federal rules of criminal procedure.

**33.** Notwithstanding above, rooted in the same issue, it is beyond doubt that the investigative agent was in complete knowledge of the omitted fact of customer's awareness of non-FDA approved status of the drugs he purchased. The fact of the drug's non-FDA approved status was mentioned on the precise website pages that other extracts have been quoted from in this complaint.

**34.** It is also inconceivable that the omission was not in the agent's knowledge as someone who has presumably painstakingly investigated this case. The omission constitutes a matter that is at the very heart of his agency's work.

**35.** As *Andersen* also makes clear, the packaging itself can give away to the customer the non-FDA approved nature of the drug. In our case, notwithstanding the clear information on the websites, the fact of a drug arriving from the under developed country of Pakistan, is more than likely to be judged as not FDA approved by a consumer of ordinary prudence. Adequate arrangements having been made for the customer to recede from the contract at any moment and claiming his money back through a simple contact with the sole official retailer CCNOW in the USA, subsidiary of a publicly held company "Digital River", leaves no doubt that the customer was fully willing to accept non-FDA regulated medicine.

**36.** In the context of an implied falsehood regarding Federal Drug Administration approval based on a package insert, the Fourth Circuit in *Mylan Laboratories, Inc. Vs. Matkari*, (7 F.3d 1130, 1139) (4<sup>th</sup> Cir, 1993) explained that: *"Mylan's claims that the defendants' falsely represented that their drugs had been 'properly approved by the FDA' must fail. First, in its complaint, Mylan nowhere points to any statement or representation in the defendants' advertising which declared 'proper FDA approval.' Moreover, that fatal deficiency cannot be cured by contentions that the very act of placing a drug on the market, with*

*standard package inserts often used for FDA-approved drugs, somehow implies (falsely) that the drug had been "properly approved by the FDA." Such a theory is, quite simply, too great a stretch under the Lanham Act."*

**37.** Based upon the material omission in the complaint and pursuant to *Jerome Franks vs. State of Delaware* (438 U.S. 154, 57 L. Ed. 2d 667, 98 S. Ct. 2674 (1978)) the court is respectfully moved to dismiss the complaint for lack of a probable cause.

**38.** Finally and notwithstanding any of the above, the Food and Drug Administration through its agent has filed this complaint. FDA's investigative authority does not include investigation of fraud rooted in veracity of advertising claims of non-prescription drugs. In fact, congress specifically and deliberately withheld this authority from the FDA by refusing to pass the FD & C Act until any provisions related to advertising were removed from it as detailed in *Gladys G. Holloway Vs. Bristol-Myers Corp.* (485 F.2d 986, 994) (DC Cir, 1973).

**39.** No subsequent legislation placed regulatory burden over OTC drug advertising veracity into FDA's hands. In *Bristol-Myers Vs. FTC* (738 F.2d 554, 559) (2<sup>nd</sup> Cir, 1984) the second circuit court of appeals noted in the context of OTC drug advertising: *"Insofar as FDA requirements and regulations are concerned, they simply do not govern this case. Not only is a different regulatory scheme involved, but generally speaking the FDA is concerned only with evaluating absolute safety and efficacy, and not with the questions of comparative safety and efficacy that arise in OTC drug advertising."*

**40.** In *Sandoz Pharmaceuticals Corp. Vs. Richardson-Vicks Inc* (902 F.2d 222, 230) (3<sup>rd</sup> Cir, 1990) the third circuit court of appeals noted: *"The FD & C Act, in contrast, is not focused on the truth or falsity of advertising claims."*

**41.** Indeed, this very district court of New Hampshire only in 2013 in an order by Honorable Justice Paul Barbadoro while refusing to defer to the FDA's judgment a matter of an OTC antibacterial soap advertising noted: Colgate-Palmolive Softsoap Antibacterial Hand Soap Marketing and Sales Practices Litigation (2013 DNH 38; 2013 US Dist LEXIS 371522013 U.S. Dist. LEXIS 37152) *"Second, plaintiffs' claims that Colgate made false and misleading statements about Softsoap Antibacterial will depend to a significant extent on how consumers interpreted Colgate's statements. The FDA does not have technical expertise related to questions of fraud and deceit."*

**42.** In the context of OTC drug marketing, FDA authority covers drug labeling and not advertising. To remove any ambiguity in the matter, this understanding over the bifurcation of authority in OTC drug marketing has also been mutually agreed between the two agencies in a working agreement entered to in 1971. In Sandoz Pharmaceuticals Corp. Vs. Richardson-Vicks Inc (902 F.2d 222, 227) (3<sup>rd</sup> Cir, 1990) the third circuit court of appeals noted: *"To resolve issues of enforcement resulting from this concurrent jurisdiction, in 1971 the FDA and the FTC agreed to a division of regulatory authority: the FDA regulates the labeling of OTC drugs while the FTC monitors the advertising for these drugs"*. See FDA/FTC Memorandum of Understanding, 36 Fed.Reg. 18,539 (1971)."

**43.** By violating the agreement with the FTC, the FDA has disregarded its own adopted stance on the matter. *"We recognize that a violation by an agency of its own rules can provide a basis for reversal of the agency action. "Where the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures. This is so even where the internal procedures are possibly more rigorous than otherwise would be required." Morton v. Ruiz, 415 U.S. 199, 235, 39 L. Ed. 2d 270, 94 S. Ct.*

1055 (1974). See also *Service v. Dulles*, 354 U.S. 363, 1 L. Ed. 2d 1403, 77 S. Ct. 1152 (1957)

44. It is clear from the complaint that the FDA has primarily concerned itself with the veracity of consumer advertising claims and made them the basis for the wire fraud allegation. In doing so, the agency has far exceeded its legal investigative and regulatory authority beyond any measure of restraint on non-prescription drug advertising.

45. Previous attempts by the FDA to exercise its authority over OTC drug advertising have been sternly rebuked in courts. For example, in *McNeilab Inc. Vs. Margaret M. Heckler* (1985 U.S. Dist. LEXIS 19169) the district court for the DC circuit noted: *"The FDA has no authority to act as "advertising czar" over consumer drug advertising--at most, the agency may discuss aspects of an ad campaign which threaten to undercut the label warnings of a drug which could otherwise be marketed safely as labeled. Any attempt to coerce compliance with advertising guidelines which go beyond the FDA's narrow concerns in the area of consumer advertising would be beyond the agency's authority and intrude upon the jurisdiction of the Federal Trade Commission."*

46. In *Endicott Johnson Vs. Frances Perkins* (63 S. Ct. 339) (1943) the Supreme Court noted *"An administrative agency is a statutory body and has no powers not specifically given it by the legislature. Interstate Commerce Commission v. Illinois C. R. Co. 215 US 452, 54 L ed 280, 30 S Ct 155; Anderson v. Dunn, 6 Wheat.(US) 204, 5 L ed 242; 1 Von Bauer, Federal Administrative Law, p 65."*

47. In *Big Lagoon Rancheria Vs. State of California* (741 F.3d 1032, 1042) (9<sup>th</sup> Cir, 2012) the 9<sup>th</sup> Circuit relying on Supreme Court noted: *"We find it in the well-worn rule that "administrative actions taken in violation of statutory authorization or requirement are of no effect." City*

*of Santa Clara v. Andrus, 572 F.2d 660, 677 (9th Cir. 1978) (citing, inter alia, Utah Power & Light Co. v. United States, 243 U.S. 389, 392, 37 S. Ct. 387, 61 L. Ed. 791 (1917)). Other courts have used different language, see, e.g., Employers Ins. of Wassau v. Browner, 52 F.3d 656, 665 (7th Cir. 1995) (unauthorized agency action may be "disregard[ed] . . . as void, a nullity"), but the upshot is the same: The law treats an unauthorized agency action as if it never existed."*

**48.** The complaint is hence not a sworn affidavit against the defendant but a sworn admission to a scandalous abuse of power not covered by any statutory authority vested in the agent or his agency by congress.

**49.** Allowing the FDA to continue this illegal encroachment of authority in the present case would lead to an unprecedented unwinding of a settled issue with an immensely thorny history of legislative debate. In Gladys G. Holloway Vs. Bristol-Myers Corp.(485 F.2d 986, 994) (DC Cir, 1972) the court of appeals for the DC circuit noted: *"The reasons why Congress chose the FTC Act, rather than the Food, Drug, and Cosmetic Act, as the vehicle for regulating the advertising of medicinal products are amply documented in the committee reports. The various alternative forms of regulation were the subject of extensive -- and sometimes acrimonious -- floor debate."*

**50.** It is therefore requested that the complaint be dismissed with prejudice as the fruit of an illegal exercise of authority.

WHEREFORE, for the reasons set foregoing reasons, the defendant prays for the following relief from this Honorable Court,

A. Dismiss the indictment for lack of probable cause, and

- B. Schedule the matter for a hearing, if necessary, after the Government's response and/or objection, and
- C. Any other relief that is fair and just.

Respectfully Submitted,

March 31, 2015

/s/James P. O'Rourke, Jr.  
James P. O'Rourke, Jr., Esq.  
PO Box 589  
Henniker, NH 03242  
Bar No. 15870  
(603) 428-3690

/s/Robert M. Napolitano, Esq.  
Robert M. Napolitano, Esq.  
Clarence Hale Mansion  
765 Congress St.  
Portland, ME 04102  
Bar No. 1021  
(207) 774-4109

Certificate of Service

I certify that this document filed will be provided to AUSA Arnold Huftalen via ECF.

/s/James P. O'Rourke, Jr.  
James P. O'Rourke, Jr., Esq.

cc: client